

WE CLAIM:

- 1 1. A pharmaceutical composition comprising sertraline or a pharmaceutically acceptable salt thereof and water, wherein the water comprises greater than about 10% w/w to about 40% w/w of the composition.
- 1 2. The composition according to claim 1, wherein the water comprises from greater than about 10% w/w to about 25% w/w of the composition.
- 1 3. The composition according to claim 2, wherein the water comprises from greater than about 10% w/w to about 15% w/w of the composition.
- 1 4. The composition according to claim 2, wherein the water comprises between about 10.5% w/w and 12% w/w of the composition.
- 1 5. The composition according to claim 1, wherein the composition further comprises one or more non-aqueous vehicles, preservatives and flavouring agents.
- 1 6. The composition according to claim 1, wherein the pharmaceutically acceptable salt comprises sertraline hydrochloride.
- 1 7. The composition according to claim 1, wherein the sertraline or pharmaceutically acceptable salt thereof is present in an amount of about 0.1 mg/ml to about 70 mg/ml.
- 1 8. The composition according to claim 1, wherein the sertraline or pharmaceutically acceptable salt thereof is present in an amount of about 15 mg/ml to about 30 mg/ml.
- 1 9. The composition according to claim 5, wherein the non-aqueous vehicle comprises one or more of ethanol, glycerine, propylene glycol or mixtures thereof.
- 1 10. The composition according to claim 9, wherein the non-aqueous vehicle comprises a mixture of ethanol and glycerine.
- 1 11. The composition according to claim 5, wherein the preservative comprises one or more of butylated hydroxytoluene, butylated hydroxyanisole, propyl gallate, ascorbic acid, ascorbyl palmitate, sodium metabisulfite, sodium bisulfite, sodium thiosulfate, sodium hydroxide, cystiene, ethylenediamine tetraacetic acid or its salts, citric acid, triethanolamine, thioglycerol, methyl paraben or propyl paraben.

1 12. The composition according to claim 11, wherein the preservative comprises
2 butylated hydroxytoluene.

1 13. The composition according to claim 5, wherein the flavouring agent comprises one
2 or more of menthol, peppermint, spearmint, citrus, strawberry, raspberry, flavour
3 blackcurrant, orange and grape fruit flavours, aspartame, saccharin sodium or mixtures
4 thereof.

1 14. The composition according to claim 1, wherein the composition is in the form of
2 an oral liquid concentrate.

1 15. The composition according to claim 1, wherein at least a portion of the water in the
2 composition is added and is not from the sertraline and/or excipients.

1 16. The composition according to claim 1, wherein the composition is free of
2 polyethylene glycol.

1 17. A process for the preparation of an orally administered liquid pharmaceutical
2 composition, the process comprising:

3 dissolving sertraline or a pharmaceutically acceptable salt thereof in one or more
4 non-aqueous vehicles to form a solution; and
5 adding water to the solution.

1 18. The process according to claim 17, further comprising:
2 filtering the solution to which water has been added; and
3 filling the filtered solution into a suitable container.

1 19. The process according to claim 17, wherein the water comprises from greater than
2 about 10% w/w to about 25% w/w of the composition.

1 20. The process according to claim 17, wherein the water comprises from 10% w/w to
2 about 15% w/w of the composition.

1 21. The process according to claim 17, wherein the water comprises between about
2 10.5% w/w and 12% w/w of the composition.

1 22. The process according to claim 17, wherein the pharmaceutically acceptable salt
2 thereof comprises sertraline hydrochloride.

1 23. The process according to claim 22, wherein the sertraline hydrochloride comprises
2 an amount of about 0.1 mg/ml to about 70 mg/ml.

1 24. The process according to claim 23, wherein sertraline hydrochloride comprises an
2 amount of about 15 mg/ml to about 30 mg/ml.

1 25. The process according to claim 17, wherein the non-aqueous vehicle comprises
2 one or more of ethanol, glycerine, propylene glycol or mixture thereof.

1 26. The process according to claim 17, further comprising adding one or both of a
2 preservative and a flavouring agent.

1 27. The process according to claim 29, wherein the preservative comprises one or
2 more of butylated hydroxytoluene, butylated hydroxyanisole, propyl gallate, ascorbic acid,
3 ascorbyl palmitate, sodium metabisulfite, sodium bisulfite, sodium thiosulfate, sodium
4 hydroxide, cystiene, ethylenediamine tetraacetic acid or its salts, citric acid,
5 triethanolamine, thioglycerol, methyl paraben, propyl paraben or mixtures thereof.

1 28. A method of treating one or more of depression, panic disorder, post-traumatic
2 stress disorder, and obsessive compulsive disorder in a patient in need thereof, the method
3 comprising administering a pharmaceutical composition comprising sertraline or a
4 pharmaceutically acceptable salt and water, wherein the water is at a concentration of
5 greater than about 10% w/w to about 40% w/w of the composition.

1 29. The method according to claim 28, further comprising diluting the pharmaceutical
2 composition in an aqueous vehicle prior to dosing.

1 30. The method according to claim 29, wherein the aqueous vehicle comprises one or
2 more of water, orange juice, ginger ale, lemon lime soda, lemonade, cranberry juice,
3 grapefruit juice, tomato juice, pineapple juice or prune juice.